Pharmaceutical
Division

Bayer Corporation
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RE: Prescribing Information Changes Regarding **Baycol**® (cerivastatin sodium tablets)

Dear Health Care Professional:

This letter provides important information on the prescribing of **Baycol**® for the treatment of hyperlipidemia. Recently, Bayer Corporation has voluntarily made changes to the prescribing information for **Baycol**® in order to provide prescribers and patients with more specific guidance on initiating therapy with the product. These changes are:

- The "Dosage and Administration" section has been revised to highlight that 0.4mg is the starting dose for **Baycol**®. *"The starting-dose of **Baycol**® is 0.4mg once daily in the evening regardless of previous lipid therapy. Since the maximal effect of cerivastatin sodium is seen within 4 weeks lipid determinations should be performed at this time and the dose adjusted based upon patient response. Only patients requiring further lipid adjustment should be titrated to 0.8mg. The dosage range is 0.2mg to 0.8mg. In patients with significant renal impairment (creatinine clearance £60 mL/min/1.73m^2) lower doses are recommended. Cerivastatin sodium may be taken with or without food."*
- In the "Warnings – Skeletal Muscle" section a statement has been added reinforcing the starting dose of **Baycol**® is 0.4mg. *"Beginning therapy above the 0.4mg starting dose increases the risk of myopathy and rhabdomyolysis."*
- The section "Patient Information about Baycol" under the heading "How should I take **Baycol**®" has a statement added that explains to the patient that 0.4mg is the starting dose of **Baycol**®: *"If you are taking **Baycol**® for the first time, your daily dose should be 0.4mg or lower."*

Bayer Corporation has made these revisions because we have received reports of muscle weakness and rhabdomyolysis during the post-marketing period. A substantial number of these cases occurred in patients receiving **Baycol**® in a manner inconsistent with product labeling: e.g. patients were treated with concurrent gemfibrozil therapy and/or received **Baycol**® 0.8mg as a starting dose. Rhabdomyolysis has been reported with all statins and is reflected in the corresponding prescribing information for all statins.

In December 1999, Bayer Corporation changed the **Baycol**® prescribing information to include a contraindication with gemfibrozil. **The combined use of cerivastatin and gemfibrozil is contraindicated due to a risk for rhabdomyolysis and concurrent use should not occur under any circumstances.**

Patients taking **Baycol**® or any other statin should be advised to report promptly to their physician unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.

We are making the above-mentioned prescribing revisions because appropriate use of Bayer products and patient safety are the primary concerns of Bayer Corporation. When used as directed, **Baycol**® effectively and safely treats patients with hyperlipidemia.

Please refer to the enclosed prescribing information or Bayer Corporation website at http://bayerpharma-na.com for the prescribing information. If you have further questions regarding this change to the prescribing information, please contact Bayer Clinical Communications at 1-800-288-8371.

Sincerely,

Richard K. Goodstein, MD

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Vice President, Scientific Relations